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FILING DATE FIRST NAMED INVENTOR APPLICATION NO. ATTORNEY DOCKET NO. CONFIRMATION NO. 10/697,824 10/29/2003 Peter Guillaume Marie Wuts 01352.US1 9543 25533 7590 03/25/2005 **EXAMINER** PHARMACIA & UPJOHN OH, TAYLOR V **301 HENRIETTA ST** ART UNIT PAPER NUMBER 0228-32-LAW KALAMAZOO, MI 49007 1625

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.	Applicant(s)	
		10/697,824	WUTS, PETER GUILLAUME	
		Examiner	Art Unit	
		Taylor Victor Oh	1625	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)⊠	Responsive to communication(s) filed on 15 A	April 2004.		
2a)□		s action is non-final.		
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
5)□ 6)⊠ 7)□				
Application Papers				
9)☐ The specification is objected to by the Examiner.				
10)	10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s)				
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)				
Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date Notice of Informal Patent Application (PTO-152) Paper No(s)/Mail Date 4/15/04 &3/5/04. Other:				

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The Status of Claims:

Claims 1-13 are pending.

Claims 1-13 have been rejected.

DETAILED ACTION

Priority

1. It is noted that this application claims a benefit of 60/422,975 filed on 11/01/02.

Drawings

2. None.

Claim Objections

Claims 4 and 5 are objected to because of the following informalities:

In claim 4, the phrase "wherein R_1 is C_1 - C_8 " is recited. There is an absence of a period in the end of the sentence. Appropriate correction is required.

In claim 5, the phrase "wherein R_2 is C_{1^-6} alkyl, C_{1^-6} alkenyl, trichloroethoxy, tri tri- C_{1^-6} alkylsilyethyl, benzyl or phenyl; "is recited. There needs a period instead of a semicolon at the end of the sentence. Appropriate correction is required.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 5 and 10, the phrase " C_{1-6} alkenyl" is recited. The expression is vague and indefinite because the alkene compound starts from two carbon atoms; it fails to define the invention properly. The examiner recommends to change from " C_{1-6} alkenyl" to " C_{2-6} alkenyl". Therefore, an appropriate correction is required.

In claim 9, the phrase " a compound of <u>Formula I</u> wherein R¹ is isobutyl" is recited. The expression is vague and indefinite because it does not indicate which compound of <u>Formula I</u> is intended. Therefore, an appropriate correction is required.

In claim 12, the phrase "a compound of Formula 1" and "compounds of Formula 2" are recited. The expression is vague and indefinite because it does not indicate which compounds of Formula 1 and Formula 2 are intended. Therefore, an appropriate correction is required.

In claim 13, the phrase " a compound of Formula 2" is recited. The expression is vague and indefinite because it does not indicate which a compound of Formula 2 is intended. Therefore, an appropriate correction is required.

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Claim 12 provides for the use of "a compound of Formula 1 for preparing compounds of Formula 2", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite, when it is essentially incomplete, and where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 13 provides for the use of "a compound of Formula 2 for preparing S-(2-aminoethyl)-2-methyl-L-cysteine", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner et al (Journal of Organometallic Chem., 346, (1988), p. 413-423) obtained from the STN Chemical Structure Search.

Brunner et al discloses 2-methyl-L-cysteine ethyl ester hydrochloride useful for making a ligand B for the procatalyst (Rh(Cod)Cl₂) in the hydrosilylation of the ketone shown in below (see example, Ligand B, page 423):

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II 120519-94-0

RL: RCT (Reactant); RACT (Reactant or reagent)

(cyclocondensation of, with pyridinecarboxaldehyde)

RN 120519-94-0 CAFLUS

CN L-Cysteine, 2-methyl-, ethyl ester, hydrochloride (9CI) (CA INDEX NAME)

Absolute stereochemistry

C SH

EtG NH2

HC1
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The instant invention, however, differs from the prior art reference in that one of the claimed substituents attached to the 2^{nd} carbon is $-CO_2$ propyl instead of $-CO_2$ ethyl and therefore, is a methyl homologue claimed compound. Since the reference teaches an acid addition salt, which can easily be remove by changing the pH, which is known in the art, the claimed compound is deemed to be unpatentable.

With respect to the absence of the salt form of the claimed compound, it is well-known in the art that it is obvious to form known acids from known salts or vise versa. In re Williams, 89 USPQ 396 (CCPA 1951). Therefore, if the skilled artisan in the art had desired to form known 2-methyl-L-cysteine ethyl ester from known 2-methyl-L-cysteine ethyl ester hydrochloride salt, it would have been obvious to the skilled artisan in the art to be motivated to form 2-methyl-L-cysteine ethyl ester as an alternative to its salt compound. HCI, This is because the skilled artisan would have known how to change the pH and remove the acid addition salt.

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Moreover, the prior art compound and the claimed compound are homologous to each other by one carbon. In order for the claimed compound to have a patentable distinction, the claimed homologous compound must possess unexpected properties not possessed by the prior art compound. In re Hass, 141 F.2d 127, 60 USPQ 548 (CCPA 1944). Furthermore, it is well-known in the art that the addition of a carbon atom to the Brunner et al compound would make the ligand B more lipophilic, thereby contributing the solubility of the procatalyst (Rh(Cod)Cl₂) to be enhanced in the hydrosilylation of the ketone. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to increase the solubility of the procatalyst (Rh(Cod)Cl₂) by adding the carbon atom to the ligand B for speeding up the reaction process. This is because the skilled artisan in the art would expect such a modification to be successful as well as efficient in the hydrosilylation process of the ketone.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrler et al (Synlett, (9), 1994, p.702-704) in view of Solomons (Organic Chemistry, 2nd ed. P.763-764).

Ehrler et al discloses an ethyl ®-2-methyl-cysteine intermediate compound used for the synthesis of the thiangazole (see abstract page on 702, left top col.).

The instant invention, however, differs from the prior art reference in that one of the claimed substituents attached to the 2^{nd} carbon is $-CO_2$ propyl instead of $-CO_2$ ethyl.

Moreover, the prior art compound and the claimed compound are homologous to each other by one carbon. In order for the claimed compound to have a patentable distinction, the claimed homologous compound must possess unexpected properties not possessed by the prior art compound. In re Hass, 141 F.2d 127, 60 USPQ 548 (CCPA 1944). Furthermore, it is well-known in the art that the addition of a carbon atom to the ethyl ®-2-methyl-cysteine intermediate compound would make the alkoxy oxide a good leaving group when a NH3 nucleophilic compound is reacted with the compound (15) (see page 703, Scheme 2, #15); this is because, with respect to the order of the reactivity of the nucleophilic substitution at an acyl carbon, Solomons has offered guidance that the alkoxy group has a greater reactivity than the amino group (see page 763, a botton section). This also means that the more the alkoxy group has alkyl moieties, the better it becomes a leaving group in comparison with the amino group due to basicities of the leaving groups(see page 763, a botton section).

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to add the carbon atom to the ethyl ®-2-methyl-cysteine intermediate

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compound in order to facilitate the overall reaction by increasing the reactivity of the intermediate processes. This is because the skilled artisan in the art would expect such a modification to be successful as well as effective as the guidance(see page 763, a botton section) shown in the Solomons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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